IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 16-129-LPS-SRF
	)	
WATSON LABORATORIES, INC.,	)	
	)	
Defendant.	)	

REPORT AND RECOMMENDATION

I. INTRODUCTION

In this Hatch-Waxman action filed by plaintiff Alcon Research, Ltd. ("Alcon") against defendant Watson Laboratories, Inc. ("Watson"), Alcon alleges infringement of United States Patent Nos. 7,947,295 ("the '295 patent") and 8,921,337 ("the '337 patent") (the "asserted patents" or the "patents-in-suit"). Presently before the court is the matter of claim construction. This order sets forth the court's recommendations of constructions for the disputed claim terms discussed in the briefing and at the *Markman* hearing held on January 13, 2017.

II. BACKGROUND

A. The Parties

Alcon is a Delaware corporation with its headquarters in Fort Worth, Texas. (D.I. 1 at ¶ 3) Alcon manufactures and sells the drug product known as Ilevro®, an FDA-approved ophthalmic suspension for topical administration to the eye. (*Id.* at ¶¶ 24, 27) Alcon is also the owner by assignment of the patents-in-suit. (*Id.* at ¶¶ 25-26)

Watson is a Nevada corporation having a place of business in Corona, California, and a place of business in Parsippany, New Jersey. (*Id.* at ¶ 4) Watson is in the business of

manufacturing and selling generic versions of branded pharmaceutical products for the United States market. (*Id.*)

B. The Asserted Patents

1. The '295 Patent

The '295 patent is entitled "Ophthalmic compositions containing a synergistic combination of two polymers," and was issued on May 24, 2011. ('295 patent) The '295 patent claims pharmaceutical compositions that are commercialized by Alcon under the trade name Ilevro® for the treatment of pain and inflammation associated with cataract surgery. (D.I. 1 at ¶ 24)

The '295 patent claims compositions that combine two polymers to produce a synergistic increase in viscosity. ('295 patent, abstract) The patent's specification explains that the claimed compositions are pharmacologically superior to the nepafenac compositions previously known because the polymeric ingredients enhance the viscosity of solution compositions, and keep the insoluble ingredients suspended or easily redispersible in suspension compositions. ('295 patent, col. 1:18-25) The compositions of the invention may be applied less frequently due to the enhanced viscosity resulting from the combination of two polymers. ('295 patent, col. 4:34-42)

2. The '337 Patent

The '337 patent is entitled "Carboxyvinyl polymer-containing nanoparticle suspensions," and was issued December 30, 2014. ('337 patent) The '337 patent claims pharmaceutical compositions that are commercialized by Alcon under the trade name Ilevro® for the treatment of pain and inflammation associated with cataract surgery. (D.I. 1 at ¶ 24)

The '337 patent claims ophthalmic compositions that are particularly suitable for delivering sparingly soluble pharmaceutical compounds, including nepafenac, into the eye.

('337 patent, abstract; col. 1:14-17; col. 2:29-33) The composition of nanoparticles are suspended in a vehicle comprising a carboxyvinyl polymer, a galactomannan, and borate to stabilize the viscosity, thereby increasing the bioavailability of the drug. (*Id.* at col. 2:25-29; 2:47-51; abstract) The inventive compositions are pharmacologically superior to the compositions previously known in the art because they form a gel when applied to the eye due to chemical interactions between the galactomannan and the borate when they come into contact with the slightly higher pH of the eye. (*Id.* at col. 2:45-47; 3:35-42; 6:40-42) This allows the drug to penetrate the eye tissue without being diluted or flushed from the eye by the tear film. (*Id.* at col. 1:20-30) Moreover, the inventive composition claims a reduction in the particle size of nepafenac in certain compositions to enhance the bioavailability of nepafenac in the topical ophthalmic suspension. (*Id.* at col. 2:47-54; col. 4:47-49) The compositions of the invention need only be applied once or twice daily due to the increased viscosity and bioavailabilty of nepafenac. (*Id.* at col. 2:34-37)

C. Procedural Posture

This case arises out of Watson's submission of Abbreviated New Drug Application ("ANDA") No. 208816 to the United States Food and Drug Administration ("FDA"), which seeks approval to market a generic version of Alcon's Ilevro® nepafenac ophthalmic suspension. (D.I. 1 at ¶¶ 1-2) Alcon is the assignee of the patents-in-suit, which are listed in the Orange Book in connection with Ilevro®. (*Id.* at ¶¶ 25-27)

Alcon filed suit against Watson on March 4, 2016, alleging that Watson's submission of ANDA No. 208816 infringes the '295 and '337 patents. (D.I. 1 at ¶ 8) Further, Alcon alleges that upon FDA approval of Watson's ANDA, Watson will infringe the patents-in-suit by making, using, offering to sell, and selling its generic nepafenac ophthalmic suspension. (*Id.* at ¶ 9)

On June 30, 2016, this action was referred by Judge Robinson for discovery and all motions to dismiss, amend, transfer, and any discovery motions permitted. The case was reassigned to Chief Judge Stark on December 21, 2016. Chief Judge Stark referred the case to the undersigned magistrate judge for all purposes through case-dispositive motions, including claim construction. (D.I. 50) The parties completed briefing on claim construction on December 30, 2016. (D.I. 39; D.I. 44; D.I. 46; D.I. 49) A *Markman* hearing was held on January 13, 2017.

III. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). However, subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015).

In construing the claims, the court should look first and foremost to the words of the claims themselves, which "are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted); *see also Eon Corp. IP Holdings v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016). Claim terms are typically used consistently throughout the patent, and "usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Phillips*, 415 F.3d at 1314 (observing that "[o]ther claims of the

patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . .").

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003) (citing *Ecolab Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1375 (Fed. Cir. 2002).

Other intrinsic evidence, including the patent specification, "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007). The specification "is not a substitute for, nor can it be used to rewrite, the chosen

claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. The prosecution history, which is also "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

A court also may rely on "extrinsic evidence," which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* ("[C]onclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court."). Overall, while extrinsic evidence may be useful to the court, it is less

reliable than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19.

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

IV. CONSTRUCTION OF DISPUTED TERMS

A. Term 1: "a viscosity enhancing amount of combination of two polymers having a synergistic effect on the composition's viscosity and wherein the combination of two polymers is selected from the group consisting of hydroxypropyl methylcellulose and guar gum; a carboxyvinyl polymer and guar gum; and hyaluronic acid and guar gum" ('295 patent, claims 10 & 18)

Alcon's proposal	Watson's proposal
The term does not require construction.	"a viscosity enhancing amount of combination of two polymers having a synergistic effect on the composition's viscosity and wherein the combination of two polymers is selected from the group consisting of hydroxypropyl methylcellulose and guar gum; a carboxyvinyl polymer and guar gum; and hyaluronic acid and guar gum, **such that if the composition comprises a carboxyvinyl polymer then the composition does not contain sodium chloride or boric acid**"

I recommend that the court adopt Alcon's proposal and decline to construe the claim term, in accordance with the doctrine of claim differentiation. The parties agree that the words of claims 10 and 18 are clear, but Watson proposes appending an additional phrase from

dependent claim 11 due to the alleged disavowal of claim scope in the '295 patent specification. Construction of this claim term "turns entirely on an interpretation of the asserted claims in light of the specification," and the parties do not rely on any evidence from the prosecution history in support of their contentions. *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001).

The exact language of Watson's proposed appended phrase appears in independent claim 1 of the '295 patent, as well as dependent claim 11. ('295 patent at col. 10:64-66; col. 11:48-50) In accordance with the doctrine of claim differentiation, the inclusion of this limitation in claims 1 and 11 demonstrates the drafter's intention to exclude the proposed limitation in independent claims 10 and 18. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."). The doctrine of claim differentiation is at its strongest in the type of case presently before the court, "where the limitation that is sought to be 'read into' an independent claim already appears in a dependent claim." *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 690 F.3d 1318, 1324 (Fed. Cir. 2012) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004)); *see also SunRace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003) (finding that the presumption is especially strong when "the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.").

The doctrine of claim differentiation creates only a presumption, which "can be overcome by strong contrary evidence such as definitional language in the patent or a clear disavowal of claim scope[.]" *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 690 F.3d

1318, 1324 (Fed. Cir. 2012). According to Watson, the '295 patent specification contains an express disavowal of claim scope sufficient to overcome the presumption of claim differentiation:

> If the compositions contain a carbomer as one of the two polymers, then the compositions of the present invention do not contain any ionic tonicity-adjusting agent, such as sodium chloride, or other ionic excipients, such as boric acid, as these ingredients have a significant, detrimental effect on the composition's viscosity.

('295 patent, col. 3:26-33) This statement does not meet the exacting standard for disavowal of claim scope. The inclusion of one sentence addressing "the compositions of the present invention" does not mean that "everything that follows in the same paragraph limits all subsequent claims." *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1358 (Fed. Cir. 2016); *see Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). Moreover, Watson has not identified how the alleged disavowal narrows the scope of the claims, and has not tied the alleged disavowal to specific claim language. *See Vehicle Operation Techs. LLC v. Am. Honda Motor Co. Inc.*, 67 F. Supp. 3d 637, 651 (D. Del. 2014) ("It is well settled law that, independent of what is written in the claims, when an inventor disavows claim scope in the prosecution history, the disavowal narrows the claim 'congruent with the scope of the surrender.'" (citing *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003)). Instead, Watson's proposed construction merely appends a phrase onto the existing claim language.

The specification of the '295 patent does not indicate that a limitation on sodium chloride or boric acid is required. To the contrary, the '295 patent specification expressly states that "[t]he embodiments described above are . . . considered to be illustrative in all respects and not restrictive, the scope of the invention being indicated by the appended claims rather than by the

foregoing description." ('295 patent, col. 10:45-54) Viewing the alleged disavowal in the context of the '295 patent as a whole, Watson's proposed limitation is not adequately supported to warrant inclusion in independent claims 10 and 18. *Unwired Planet*, 829 F.3d at 1358. Moreover, it is well-established that the absence of an embodiment in the '295 patent specification containing a carbomer in combination with either sodium chloride or boric acid is insufficient to constitute a disavowal. *See Cadence Pharm., Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1369 (Fed. Cir. 2015) ("[E]ven if all of the embodiments discussed in the patent included a specific limitation, it would not be proper to import from the patent's written description limitations that are not found in the claims themselves."); *Unwired Planet*, 829 F.3d at 1359.

Watson also points to a portion of the '295 patent specification which teaches that synergistic viscosity can be significantly compromised[1] with the addition of small amounts of salts or acids during routine adjustment of the solution pH:

> If the compositions contain a carbomer, it is critical that the compositions are formulated so that the target pH is not exceeded. Once a target pH has been exceeded in the compositions containing a carbomer, adding an acid such as hydrochloric acid to adjust the pH downward can compromise the synergistic viscosity. It is known that relatively small amounts of acid or salts, on the order of 0.005%, can have a significant effect on the viscosity of compositions containing a carbomer.

('295 patent, col. 3:35-44) However, the Federal Circuit has declined to find disavowal based on "criticism of a particular embodiment" or general descriptions of what constitutes "the present

[1] The '295 patent specification does not suggest that the addition of sodium chloride or boric acid to the carbomer has the effect of eliminating the synergistic effect of combining polymers. If the presence of sodium chloride or boric acid were to cause a complete elimination of the synergistic effect on viscosity, the composition would fall outside the claims, which require the compositions to exhibit a viscosity "greater than 150% of the simple sum of two respective single polymer solutions containing only one of the two polymers." ('295 patent, col. 11:44-46; col. 12:40-42)

invention." *Thorner*, 669 F.3d at 1366; *Unwired Planet*, 829 F.3d at 1358-59; *see also Microthin.com, Inc. v. SiliconeZone USA, LLC*, 377 F. App'x 8, 11 (Fed. Cir. 2010). The alleged disavowal in the specification encompasses all ionic tonicity-agents and all ionic excipients, and yet the embodiment described in Table 1 contains the carbomer Carbopol® in combination with sodium hydroxide or hydrochloric acid ('295 patent, col. 4:56-65), which are pH-adjusting ionic excipients according to the '295 patent specification (*Id.* at col. 3:13-21) (identifying as excipients a list including tonicity-adjusting agents and pH-adjusting agents).

The Federal Circuit's decision in *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.* is distinguishable from the facts presently before the court because the specification of the patents-in-suit in *SciMed* contained multiple, consistent instances of express disavowal in the abstract, the discussion of the disadvantages of the prior art, the summary of the invention, and the detailed description of the preferred embodiments. 242 F.3d 1337, 1344-45 (Fed. Cir. 2001). In contrast, Watson's argument hinges primarily on one sentence in the detailed description of the invention which refers to "the compositions of the present invention," but does not precisely indicate that it encompasses all embodiments. ('295 patent, col. 3:26-33) Other cited passages in the specification of the '295 patent express concern about the effect of salt or acid on the viscosity of the claimed compositions, but fall short of constituting an express disavowal. (*Id.* at col. 3:26-44; col. 8:35-9:13) For instance, although examples 7 and 8 of the '295 patent show that adding salt or boric acid can reduce a carbomer composition's viscosity, illustrating a known effect does not rise to the level of an express disavowal of any amount of ionic tonicity-adjusting agent or ionic excipient in the claimed compositions. (*Id.* at 8:35-9:13) This is evident in the '295 patent because the compositions of the invention contain ionic pH-

adjusting agents, such as sodium hydroxide and hydrochloric acid, despite their known effect on synergistic viscosity. (1/13/17 Tr. at 11:2-10; '295 patent, col. 4:55-65; col. 3:38-44)

Other cases cited by Watson in support of its disavowal arguments are also inapposite. In *Chicago Board Options Exchange, Inc. v. International Securities Exchange, LLC*, the Federal Circuit concluded that the patent specification disavowed the traditional open-outcry or floor-based trading system by repeatedly and consistently describing the unsustainability of manual and partially automated exchanges. 677 F.3d 1361, 1372 (Fed. Cir. 2012). In contrast, the '295 patent specification identifies embodiments which include ionic tonicity-adjusting agents and ionic excipients, despite the negative impact of these compounds on viscosity. ('295 patent, col. 4:55-65) The instant case is also distinguishable from the Federal Circuit's decision in *SafeTCare Manufacturing, Inc. v. Tele-Made, Inc.*, which concluded that the specification disavowed a motor using a pulling force because the patentee repeatedly emphasized that the motor exerted a pushing force and stated that this attribute distinguished the invention over the prior art. 497 F.3d 1262, 1270-71 (Fed. Cir. 2007). The '295 patent specification offers no indication that the exclusion of sodium chloride, boric acid, or any other ionic excipient is necessary to overcome a prior art reference.

In sum, the parties do not dispute the meaning of the actual claim term. Watson's attempt to append additional language to independent claims 10 and 18 of the '295 patent would have the improper effect of rewriting the claim. *See Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1374 (Fed. Cir. 2014) ("Where the meaning of a claim term is clear, as it is here, we do not rewrite the claim to preserve its validity."). For the foregoing reasons, I recommend that the court decline to construe the first disputed claim term found in independent claims 10 and 18 of the '295 patent.

B. Term 2: "sparingly soluble particulate compound" ('337 patent, claim 1)

Alcon	Watson
"a particulate compound or pharmaceutical agent that has a solubility limit in water at 25° C. in the range of 0.001 to 0.1 w/v %"	The term does not require construction.

I recommend that the court adopt Watson's proposal and decline to construe the claim term. Independent claim 1 of the '337 patent recites:

> 1. A topically administrable aqueous ophthalmic suspension composition comprising:
> carbomer at a concentration of 0.1 to 0.5 w/v %;
> guar at a concentration of 0.1 to 0.4 w/v %;
> borate at a concentration of 0.4 to 2.0 w/v %; and
> a sparingly soluble particulate compound, said compound having a solubility in water at 25° C. of 0.001 to 0.1 w/v % and a particle size of 50 to 700 nm, and wherein said sparingly soluble particular compound is nepafenac at a concentration of 0.25 to 0.35 w/v %.

('337 patent, col. 8:39-48) The parties agree that the specification defines a "sparingly soluble particulate compound" as "a compound or pharmaceutical agent that has a solubility limit in water at 25° C. in the range of 0.001 to 0.1 w/v %." (*Id.* at col. 4:33-35) There is no dispute that nepafenac is the "sparingly soluble particulate compound" referenced in claim 1 of the '337 patent. Construction of the term is therefore not necessary, and could result in ambiguity due to the potentially different meanings of "solubility" in the claim language and "solubility limit" in Alcon's proposed construction.

C. Term 3: "particle size" ('337 patent, claims 1 & 15)

Claim	Alcon	Watson
1	The text comprises two separate limitations that should be construed as follows: "a sparingly soluble particulate compound, said compound having an average particle size of 50 to 700 nm" "and wherein said sparingly soluble particulate compound is nepafenac at a concentration of 0.25 to 0.35 w/v %"	"0.25 to 0.35 w/v % nepafenac, wherein the nepafenac particles have a particle size between 50 and 700 nm"
15	"0.3 w/v % nepafenac having an average particle size of 50 to 700 nm"	"0.3 w/v % nepafenac, wherein the nepafenac particles have a particle size between 500 and 700 nm"

I recommend that the court adopt Watson's proposed construction with respect to the "particle size" term that appears in claims 1 and 15 of the '337 patent, because different words in a patent claim are generally presumed to carry different meanings. *See August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1284 (Fed. Cir. 2011). Claims 1 and 15 of the '337 patent identify a composition having "a particle size of 50 to 700 nm," describing a range of particle sizes. ('337 patent, col. 8:46; col. 9:16-17) Dependent claim 14 claims a composition having "an average particle size of 400 nm." (*Id.* at col. 9:13) The language of the claims supports a construction which recognizes the presumption that the drafter intended to include the phrase "average particle size" in dependent claim 14 to impart a different meaning to the claim term than the references to "a particle size" in claims 1 and 15. *See Phillips*, 415 F.3d at 1314-15 ("Differences among claims can also be a useful guide in understanding the meaning of particular claim terms."); *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987) ("There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims.").

The lack of an antecedent basis for the term "an average particle size" in dependent claim 14 further supports Watson's proposed construction recognizing a distinction between the use of "particle size" and "average particle size" in the claims. "The requirement that each claim term [must] have an antecedent basis is a rule of patent drafting, administered during patent examination." *Comcast Cable Commc'ns, LLC v. Sprint Commc'ns Co., LP*, 38 F. Supp. 3d 589, 616 (E.D. Pa. 2014) (citing *Energizer Holdings, Inc. v. Int'l Trade Comm'n,* 435 F.3d 1366, 1370 (Fed. Cir. 2006)). To provide a proper antecedent basis, "a claim must introduce a given term using an indefinite article (e.g., 'a' or 'an') before referring to it in definite form, using 'the' or 'said.'" *Id.* (citing Morgan D. Rosenberg, *The Essentials of Patent Claim Drafting* app. B, at 183 (2012)). The use of the indefinite article "an" before the words "average particle size" in claim 14 therefore suggests that it does not refer to "a particle size" in the preceding independent claim 1. Pursuant to the Manual of Patent Examining Procedure ("MPEP"), the examiner would have been required to reject claim 14 for indefiniteness due to the lack of antecedent basis if "an average particle size" was meant to refer to "a particle size" in claim 1. *See* MPEP § 2173.05(e)-(f) (9th ed. Nov. 2015). The lack of a § 112 rejection for indefiniteness is therefore a strong indicator that the examiner believed "particle size" and "average particle size" to have separate meanings. Accordingly, "particle size" should be construed in accordance with Watson's proposed construction to preserve the distinction between this term and "an average particle size" appearing in claim 14.

The specification is not inconsistent with Watson's proposed construction because the terms "particle size" and "average particle size" are not used interchangeably throughout the specification. The Brief Summary of the Invention refers to "particle size" in the context of a range of particle sizes between 50 and 700 nm: "The present inventors have also found that a

reduced particle size of 50 to 700 nm improves the bioavailability of such compounds in target tissues using topical ophthalmic suspensions." ('337 patent, col. 2:51-54) This is consistent with the references to a "particle size of 50 to 700 nm" in claims 1 and 15. Example 4 sets forth a single embodiment of the claimed invention, which explains that "the nepafenac particle size was reduced to approximately 400 nm," without identifying the 400 nm particle size as an average. ('337 patent, col. 7:56-57) This description is not inconsistent with the specification's earlier identification of 400 nm as the patent's "most preferred average particle size," because the 400 nm "particle size" of this particular embodiment falls within the designated particle size range of 50 to 700 nm identified in the Brief Summary of the Invention and claims 1 and 15.

The reference to "an average particle size of 50 to 700 nm" in the Detailed Description of the Invention does not alter the court's analysis because the specification refers to "average particle size" in connection with the preferred embodiments of the claimed composition, as opposed to the invention generally:

> The present inventors have found that decreasing the particle size of nepafenac in certain compositions of the present invention enhances the bioavailability of nepafenac. Preferred compositions accordingly have an average particle size of 50 to to 700 nm [sic], a more preferred average particle size of 100 to 600 nm, and a most preferred average particle size of 400 nm.

('337 patent, col. 4:47-53) In this context, the word "average" has the effect of designating an additional limitation in a preferred embodiment. The "most preferred" embodiment of the additional limitation from the Detailed Description of the Invention appears in dependent claim 14. (*Id.* at col. 9:12-13)

The Federal Circuit's decision in *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312 (Fed. Cir. 2015) is not sufficiently analogous to persuade the court to alter its interpretation of the intrinsic record in the present matter. The claims at issue in *Ethicon* refer to a "clamping

pressure" and an "average" clamping or coaptation pressure in describing a feature of the invention. *Id.* at 1316. The Federal Circuit determined that the terms were used interchangeably because both referred to a key range of 60 psi to 210 psi, and held that the claims referred to average clamping or coaptation pressure regardless of whether the word "average" was expressly recited by the claims. *Id.* However, the Federal Circuit's decision in *Ethicon* was decided in the context of an indefiniteness argument relating to the measurement of a clamping pressure, and was not an issue of claim construction to determine whether the term "clamping pressure" should be understood to be an "average clamping pressure." *Id.* at 1316-17.

The intrinsic evidence in this case is sufficient to support Watson's proposed construction. *See Ruckus Wireless, Inc. v. Innovative Wireless Solutions, LLC*, 824 F.3d 999, 1003 (Fed. Cir. 2016) ("Legal error arises when a court relies on extrinsic evidence that contradicts the intrinsic record."). However, the extrinsic evidence cited by the parties further supports the court's conclusion. Watson's expert, Dr. Mark Prausnitz, indicates that "a particle size of 50 to 700 nm" would be understood by a person of ordinary skill in the art to mean a distribution of nepafenac particle sizes falling within a range of 50 to 700 nm. (D.I. 45 at ¶ 17) Dr. Prausnitz bolsters his conclusion with citations to a pharmaceutical textbook, which explains that "[p]articles can be classified by determining the number of particles in successive size ranges." (*Id.*, Ex. 4 at 706-07) In contrast, an "average particle size" contains an additional limitation for a particle size distribution, representing the average of all particle sizes in the distribution. (*Id.* at ¶ 20; Ex. 4 at 707)

For the foregoing reasons, I recommend that the court adopt Watson's proposed construction of "particle size."

V. CONCLUSION

For the reasons set forth above, I recommend the disputed terms be construed as follows:

Claim Term	**Recommended Construction**
"a viscosity enhancing amount of combination of two polymers having a synergistic effect on the composition's viscosity and wherein the combination of two polymers is selected from the group consisting of hydroxypropyl methylcellulose and guar gum; a carboxyvinyl polymer and guar gum; and hyaluronic acid and guar gum" ('295 patent, claims 10 & 18)	No construction required.
"sparingly soluble particulate compound" ('337 patent, claim 1)	No construction required.
"particle size" ('337 patent, claims 1 & 15)	Claim 1: "0.25 to 0.35 w/v % nepafenac, wherein the nepafenac particles have a particle size between 50 and 700 nm" Claim 15: "0.3 w/v % nepafenac, wherein the nepafenac particles have a particle size between 500 and 700 nm"

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. Appx. 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, http://www.ded.uscourts.gov.

Dated: February 15, 2017

Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE